8EHQ-1001-14915

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October 26, 2001

8EHQ-01-14915

Via Federal Express

Document Processing Center (7407)
Room G99 East Tower
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460-0001

Contain NO CBI

Dear 8(e) Coordinator:

8EHQ-01-14915

This letter is to inform you of the results of a recently completed developmental toxicity study with the above-referenced test material.

The test material was administered by oral gavage as suspensions in water to groups of 22 time-mated rats at dosages of 0, 50, 100, or 400 mg/kg/day over days 6-20 of gestation (G). Body weight, food consumption, and clinical observation data were recorded during the in-life portion of the study. On day 21G, the females were euthanized and examined grossly; the uteri were removed, weighed, and uterine content data were collected. Each fetus was weighed, sexed, and examined externally and skeletally. Approximately 50% of the fetuses underwent fresh visceral and fixed head evaluations.

There was no compound-related mortality nor were there any compound-related gross postmortem observations at any level tested. Maternal toxicity was evident at 400 mg/kg/day. Compound-related clinical observations were seen and included alopecia, scabs, vaginal discharge, and stained and/or wet fur. Additional evidence of maternal toxicity included marked significant reductions in maternal body weight, weight gain, and food consumption. Developmental toxicity evident as a significant reduction in mean fetal weight (87% of control) and an increased incidence of delayed skull bone ossification was observed at 400 mg/kg/day. There was no compound-related embryofetal mortality nor were there any compound-related fetal malformations.

Maternal toxicity was evident at 100 mg/kg/day as significant compound-related reductions in maternal weight, weight gain, and food consumption. There was no evidence of developmental toxicity at 100 mg/kg/day.

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There was no adverse, compound-related maternal or developmental toxicity at 50 mg/kg/day.

Under these experimental conditions, the findings described above appear to be reportable, based upon guidance given in the EPA TSCA Section 8(e) Reporting Guide (June 1991). However, we do not believe these findings represent a unique hazard to the conceptus.

Sincerely,

A. Michael Kaplan

A. Michael Kaplan, Ph.D.
Director – Regulatory Affairs

AMK/SMM:clp
(302) 366-5260